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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,212	12/04/2001	Jeong S. Lee	ACSC 60308 (2864)	7883

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EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

7/6/05

Office Action Summary	Application No. 10/010,212	Applicant(s) LEE ET AL.	
	Examiner Matthew F. DeSanto	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 9, 19, 21, 23-33, 35 and 42-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-5, 9, 19, 25, 27-29 and 42 is/are allowed.
- 6) ☒ Claim(s) 21, 23, 24, 26, 30-33, 35 and 43-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/4/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 30, 43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. With regards to claims 30, 43 the amendment to the claims are unclear as to the specific characteristics of the polymeric material with regards to how the polymeric material interacts with the inflation lumen. The claim is indefinite with regards to how the polymeric material is related to the inflation lumen. Therefore, the examiner's interpretation is that the polymeric member makes up the inflation lumen on the inner surface and the outer surface of the polymeric member interacts with the outer periphery of the inflation lumen.

Claim Rejections –

35 USC § 102 or 35 USC § 103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 21, 23, 24, 26, 30-33, 35, and 43-46 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Estrada et al. (USPN 6193686).

Estrada et al. discloses a balloon (15) catheter with an elongated shaft having an inflation lumen, a guide-wire receiving lumen, a proximal shaft section comprising a proximal tubular member, a distal shaft section comprising an outer tubular member, and an inner tubular member and a reinforcing member (27) formed of a first polymeric (PEEK) material having a glass transition temperature greater than the glass transition temperature of a second polymeric material (Nylon 12) forming the distal portion of the proximal tubular member. (Figures 1 – 11, Column 5, lines 8-45, and entire reference).

The examiner read through the specification and found the chemical compounds that makeup the reinforcing member and the proximal tubular member of the prior art and then looked up there glass transition temperatures on the internet. The examiner found the temperatures on the following two websites:

http://www.zeusinc.com/peek_resin.asp (for nylon) and
www.sigmaaldrich.com/img/assets/3900/Thermal_Transitions_of_Homopolymers.pdf –
(for PEEK).

After reviewing the websites it is inherent that the PEEK will have a higher glass transition temperature than nylon and thus forming the basis for the rejection on this patent application.

4. Claims 21, 23, 24, 26, 30-33, 35, and 43-46 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Happ et al. (USPN 6575958).

Happ et al. discloses a balloon (22) catheter with an elongated shaft having an inflation lumen, a guide-wire receiving lumen, a proximal shaft section comprising a proximal tubular member, a distal shaft section comprising an outer tubular member, and an inner tubular member and a reinforcing member (130) formed of a first polymeric material (col. 5, lines 49-68) having a glass transition temperature greater than the glass transition temperature of a second polymeric material (Nylon 12) forming the distal portion of the proximal tubular member. (Figures 1 – 19, Column 4, line 65 – Column 5, line 4, and entire reference).

The examiner read through the specification and found the chemical compounds that makeup the reinforcing member and the proximal tubular member of the prior art and then looked up there glass transition temperatures on the internet and the temperatures on the following two websites:

http://www.zeusinc.com/peek_resin.asp (for nylon) and
www.sigmaaldrich.com/img/assets/3900/Thermal_Transitions_of_Homopolymers

.pdf – (for PEEK).

After reviewing the websites it is inherent that the PEEK (reinforcing member) will have a higher glass transition temperature than nylon (proximal tubular member) and thus forming the basis for the rejection on this application.

Claim Rejections - 35 USC § 103

5. Claims 23, 24, 26, 30-33, 35, and 43-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verbeek (USPN 5690613), and further in view of Rau et al. (USPN 6024722) and in view of Samuelson et al. (USPN 6,165,166).

Verbeek discloses a balloon (35) catheter with an elongated shaft having an inflation lumen, a guide-wire receiving lumen, a proximal shaft section comprising a proximal tubular member (50) with a mandrel (30), a distal shaft section comprising an outer tubular member (80), and an inner tubular member (70) and a reinforcing member (13,17) formed of a first polymeric material polymeric reinforcing member around or within the proximal portion of the inner tubular member or the distal portion of the proximal tubular member, wherein a second polymeric material is used to form the distal portion of the proximal tubular member, as well as having a mandrel within the inflation lumen. (Figures 1A, 1B, 1C, and entire reference), but the reference fails to disclose the polymeric reinforcing member is formed from a thermoset or thermoplastic polyimide, and wherein the second polymeric material is formed from a nylon or polyether block amide, polyurethane, and adhesive polymer and wherein the first polymeric material has a higher glass transition temperature than the second polymeric material.

Rau et al. discloses the use of thermoplastics and thermoset polyimide in balloon catheters because of the high strength and flexibility. (Column 1, line 32-45, and entire reference)

Samuelson et al. discloses a catheter with different layers and each layer has a different glass transition temperature, and wherein the outer layer has the greatest glass transition temperature, as compared to the inner most layer, which has the lowest glass transition temperature. The invention discloses that varying the glass transition temperature provides many advantages. (Column 4, lines 7-37).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the teachings of Verbeek with the teachings of Rau et al. and Samuelson et al. because Rau et al. discloses the advantage of using a thermoset polyimide in a catheter wall because of the high strength and flexibility and Samuelson et al. disclosed using different polymers with different glass transition temperatures.

Allowable Subject Matter

6. Claims 1-5, 9, 19, 25, 27-29, and 42 are in condition for allowance.

Response to Arguments

7. Applicant's arguments with respect to all the claims have been considered but are not persuasive because of applicant arguments' are drawn to the polymeric member that is within the proximal shaft and also makes up the inflation lumen. This is similar to the amendments that were added in the last office action. The examiner still holds his rejection because the polymeric member is a tubular structure and therefore has a tubular inner surface as well as defines the inflation lumen on the inner surface and is connected to the tubing that also creates the inflation

lumen on the outer surface because the polymeric member doesn't extend the entire length of the proximal shaft, therefore the portion of the inflation lumen that the polymeric member doesn't consist of is the portion of the proximal shaft and therefore the polymeric member interacts with the outer periphery of the inflation lumen.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F. DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Matthew DeSanto
Art Unit 3763
October 17, 2005



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